

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of

Schneider et al

Atty. Ref.: 1201-98

Serial No. To be Assigned

Group:

Filed: February 20, 2004

Examiner:

For: STABLE MICROBUBBLE SUSPENSIONS AS
ENHANCEMENT AGENTS FOR
ULTRASOUND ECHOGRAPHY AND DRY FORMULATIONS
THEREOF

* * * * *

February 20, 2004

Assistant Commissioner for Patents
Washington, DC 20231

Sir:

INFORMATION DISCLOSURE STATEMENT


Applicants respectfully submit this Information Disclosure Statement pursuant to 37 C.F.R. §§ 1.97 and 1.98 in order to comply with the duty of disclosure under 37 C.F.R. § 1.56. These references are listed on the attached modified PTO Form No. 1449. It is respectfully requested that the information be expressly considered during the prosecution of this application and that the references be made of record therein and appear among the "References Cited" on any patent to issue therefrom.

A copy of each of the listed references may be found in the file of Serial No. 08/740,653 filed October 31, 1996 and now pending before Examiner Hartley.

It is believed that no fees are due in connection with this Information Disclosure Statement. However, should any fees be due, the commissioner is authorized to charge Deposit Account No. 14-1140 for such fees. Early and favorable action is earnestly solicited.

Respectfully submitted,

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Based on Form PTO-1449 (3/90) LIST OF REFERENCES CITED BY APPLICANT (Use several sheets if necessary)				ATTY. DOCKET NO. 1201-98		CONT. OF SERIAL NO. 09/770,216	
				APPLICANTS: Schneider, et al			
				FILING DATE February 20, 2004		GROUP	
U.S. PATENT DOCUMENTS							
EXAMINER INITIAL		DOCUMENT NUMBER	ISSUE DATE	NAME	CLASS	SUB- CLASS	FILING DATE IF APPROPRIATE
	AA	5,730,954	3/1998	Albayrak et al.			
	AB	5,599,523	2/1997	Beller			
	AC	5,837,221	11/1998	Bernstein et al.			
	AD	4,832,941	5/1989	Berwing			
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	AF	4,957,656	9/1990	Cerny			
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	AM	4,370,349	1/1983	Evans			
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	AEE	4,927,623	5/1990	Long			
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FILING DATE January 29, 2001		GROUP 1617

	AFF	4,192,859	3/1980	Mackanness, et al			
	AGG	4,027,007	5/1977	Messina			
	AHH	5,601,085	2/1997	Østensen			
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	ALL	4,442,843	4/1984	Rasor			
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	APP	5,425,366	6/1995	Reinhardt			
	AQQ	5,501,863	3/1996	Rössling et al.			
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	ASS	4,544,545	10/1985	Ryan			
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	ARRR	5,123,414	6/1992	Unger			
	ASSS	5,149,319	9/1992	Unger			
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		DOCUMENT NUMBER	PUBLIC- ATION DATE	COUNTRY	CLASS	SUB- CLASS	TRANSLATION	
							YES	NO
	BA	ZA 910961 (Albayrak)		South Africa				
	BB	EP A 458 745 (Bichon et al.)	11/1991	EP				
	BC	0 401 952 A2	12/1990	Europe				
	BD	EP 359 246 A2 (Cerny)	3/1990	EP				

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	BE	EP 359 246 A3 (Cerny)	3/1990	EP				
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	BG	WO 95/22994	8/1995	PCT				
	BH	WO 99/27981	6/1999	PCT				
	BI	WO 99/07415	2/1999	PCT				
	BJ	WO 84/02838 (Feinstein)	8/1984	PCT				
	BK	WO 89/05160 (PCT DE 988/00751) (Fritzsche)	6/1989	PCT			X	
	BL	WO 92/05806 (Giddey)	4/1992	PCT				
	BM	WO 92/19273 (EP 0 583 390) (Goldenberg)	11/1992	PCT				
	BN	DE A 41 27 442 (Gross)	2/1993	Germany			X	
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	BQ	WO 91/12823 (Illum et al.)	9/1991	PCT				
	BR	WO 93/13802	7/1993	PCT				
	BS	WO A 92/17212 (EP 0 576 519) (Klaveness)	10/1992	PCT				
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	BV	CA 2077383 (EP 0535387) (Krone)	3/1993	Canada				
	BW	WO 93/5819 (EP 0 605 477) (Quay)	4/1993	PCT				
	BX	WO 94/16739 (Quay)	8/1994	PCT				
	BY	WO 88/7365 (Ranney)	10/1988	PCT				
	BZ	EP A 131 540 (Rasor & Tickner)	1/1985	EP			X	
	BAA	GB 213 5647 (Ridgway)	9/1984	Great Britain				
	BBB	WO 91/15244 (Schneider et al)	10/1991	PCT				
	BCC	EP A 554 213 (Schneider)	4/1993	EP				
	BDD	WO-A-85/02772 (Schroder)	7/1985	PCT				
	BEE	NZ 253115 (Stein)	1/1996	New Zealand				
	BFF	WO 92/18164 (Sutton)	10/1992	PCT				
	BGG	WO-A-80/2365 (Tickner et al.)	11/1980	PCT				
	BHH	WO 91/09629 (Unger)	7/1991	PCT				

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	BII	WO 92/22247 (Unger)	12/1992	PCT				
	BJJ	WO 92/17514 (Unger)	10/1992	PCT				
	BKK	WO 93/06869 (Vanderipe)	4/1993	PCT				
	BLL	EP A 324 938 (Widder et al.)	7/1989	EP				
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	CA	Biochemistry/Ed. Stryer - 2 Ed., San Francisco, Freeman, pp. 208-09 (1981)						
	CB	Concise Encyclopedia Of Polymer Sci. and Engin., Wiley, pp. 12-13 (1990)						
	CC	Encyclopedia of Polymer Science and Engineering, 2nd ed., 10, p. 95, Wiley & Sons, 1987)						
	CD	Encyclopedia of Polymer Science and Engineering, pp. 164-69, Wiley & Sons, 1985						
	CE	"Freon" Fluorocarbons Properties and Applications," DuPont Technical Bulletin, pp. 1-11 (1964)						
	CF	"Freon" DuPont Technical Bulletin, pp. 1-10 (1987)						
	CG	Gas Encyclopedia, Elsevier Publisher (1976), CCIF3						
	CH	Handbook of Pharmaceutical Excipients: Am. Pharm. Ass. 181-183 (1986)						
	CI	"Lecithin" in Rompp Chemie Kexikon, p. 2474 (1989-92)						
	CJ	"Lecithin" in Blakiston's Gould Medical Dictionary, 4th Ed., N.Y., McGraw-Hill, p. 749 (1979)						
	CK	"Lecithin" in Dorland's Illustrated Medical Dictionary, 26 Ed., Philadelphia, Saunders, p. 721 (1981)						
	CL	Remington's Pharmaceutical Sciences: Mack Publ. Comp., 295-298: 736; 1242-44 (1975)						
	CM	Barnhart et al., Invest. Radiol, 25, 162-164 (1990) "Characterics of Alburnex"						
	CN	Benita et al., Journal of Pharmaceutical Science, 73, pp. 1721-1724 (1984) "Characterization of Drug Loaded Polydilactide Microspheres"						
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CQ	Bommer et al., Abstract of the 54 Scient. Sessions, Circulation <u>64</u> , - 203, Abst. 770 (1981)
CR	Crommelin et al., Pharm. Res., pp. 159-163 (1984) "Stability of Liposomes on Storage ..."
CS	Crommelin et al., Liposomes as Drugs Carriers Symp., pp. 88-93 (1986) "Freezing and Freeze Drying of Liposomes"
CT	de Gruyter, "Phospholipids", <u>Concise Encyclopedia of Biochemistry</u> , Berlin, pp. 348-49 (1983)
CU	deJong, et al., <u>Ultrasonics</u> , 1992, Vol. 30, No. 2, pp. 95-103, "Absorption and scatter of encapsulated gas filled microspheres ..."
CV	deJong, et al., <u>Ultrasonics</u> , 1991, Vol. 29 Jul., pp. 324-330, "Principles and recent developments in ultrasound"
CW	Edwards, et al. <u>J. Acoust. Soc. Am.</u> , Vol. 70, No. 3 (1983), "Scattering of focused ultrasound by spherical microparticles"
CX	Epstein, et al., <u>J. Chem. Physics</u> , Vol. 18, No. 11, pp. 1505-1509, Nov. 1950, "On the Stability of Gas Bubbles in Liquid-Gas Solutions"
CY	Feinstein, et al., <u>JACC</u> , Vol. 16, No. 2, 8/90:316-24, "Safety and Efficacy of a New Transpulmonary Ultrasound Agent...", <u>Amer. Hearts Assn. Monograph Circulation</u> , Part II, Vol. 72, No. 4, Oct. 1985, <u>Abstracts of the 58th Scientific Ses.</u>
CZ	Feinstein, et al., <u>Am. J. of Physiologic Imaging</u> , 1:12-18 (1986), "Myocardial Contrast Echocardiography ..."
CAA	Feinstein, <u>J. of the Amer. Coll. of Cardiol.</u> , 8:251-253 (1986) "Myocardial Perfusion Imaging ..."
CBB	H. Fessi, et al., "Nanocapsule formation by interfacial polymer deposition...", <u>Int. J. Pharm.</u> , 1989, Vol. 55, No. 1, pp. R1-R4
CCC	Fieser and Fieser, <u>Organic Chemistry</u> , 3rd ed. (1956) p. 847
CDD	Fobbe, et al., <u>Furtschr Rontgenstr.</u> , 154.3 (1991) 242-245, "Farbkodierte Duplexsonographische und Ultraschallkontrast mittel ..."
CEE	Ganguly et al., "Structure of hollow polystyrene microspheres..." <u>J. Microencapsulation</u> , Vol. 6, No. 2, 193-198 (1989)
CFF	Gardner, et al., (1988), "A Survey of Intraocular Gas Use in North America," <u>Arch. Ophthalmol.</u> , 106:1188-1189
CGG	Goldberg et al., <u>Radiology</u> , <u>177</u> , pp. 713-7 (1990) "Hepatic Tumors ..."

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CHH	Gregoriadis, Gregory, <u>Liposome Technology</u> , Vol. I, "Preparation of Liposomes", CRC Press, pp. 172-77.
CII	Gursel et al, "Influence of membrane components ...", J. Microencapsulation Vol. 12 No. 6, 661-669, 1995.
CJJ	Hazemoto et al, "pH-Sensitive Liposomes Composed ...", Chem. Pharm. Bull 38(3), 748-751, 1990.
CKK	Helzel, <u>Fortschr. Rontgenste</u> , 140, pp. 337-340 (1984) "Erste Erfahrungen ..."
CLL	Henry-Michelland et al., <u>Colloids and Surfaces</u> , 14, pp. 269-276 (1985) "Lyophilization and Rehydration of Liposomes"
CMM	Jacobs, "Intraocular gas measurement using A-scan ultrasound," <u>Current Eye Research</u> , Vol. 5, No. 8, 1986, pp. 575-578
CNN	Keller et al, <u>Circulation Res</u> , 65, 458-467 (1989) "The Behavior of Sonicated Albumin ..."
COO	Krause et al., <u>International Journal of Pharmaceutics</u> , 27, pp. 145-155 (1985) "Polylactic acid nanoparticle. . ."
CPP	Levene et al, <u>J. Acoust. Soc. Am.</u> , 87 (Suppl) 69 (1990) "Characterization of Alburnex ..."
CQQ	Lin et al, "The Effect of Positive and Negative ...", <u>Biochimica et Biophysica Acta</u> 1147, 237-244, 1993.
CRR	Lincoff, et al., "Intravitreal Longevity of Three Perfluorocarbon Cases, <u>Arch. Ophthalmology</u> , 98:1610-1611 (1980)
CSS	Lincoff, et al., "Intravitreal Expansion of Perfluorocarbon Bubbles," <u>Arch. Ophthalmology</u> , 98:1646 (1980)
CTT	Lincoff, et al., "The Perfluorocarbon Gases in the Treatment of Retinal Detachment," <u>Ophthalmology</u> , 90(5):546-551 (1983)
CUU	Lincoff, et al., "Perfluoro-n-butane: A Gas for Maximum Duration Retinal Tamponade," <u>Arch. Ophthalmology</u> , 101:460-463 (1983)
CVV	K. Makino, "Preparation and in vivo degradation properties...", <u>Chem. Pharm. Bull.</u> , (1985), Vol. 33, No. 3, pp. 1195-1201
CWW	Mattrey et al., <u>Radiology</u> , 148, pp. 759-762 (Dec. 1982) "UHM Sound; Perfluorooctylbromide ..."
CXX	Maza et al, "Solubilization of unilamellar ...", <u>Journal of Controlled Release</u> 37 (1995) 33-42.

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CYY	Chem Abs., Vol. 102. No. 3, 21 (Jan. 1985), Maynard et al., "Ultrasonic absorption by liposomes"
CZZ	Meltzer, et al., <u>Ultrasound in Med. & Biol.</u> , Vol. 7, No. 4, pp. 377-384, 1981, "Transmission of Ultrasonic Contrast Through the Lungs"
CAAA	Miller et al., <u>J. Amer. Soc. Anesthesiol.</u> , <u>36</u> 339-351 (1971) "Physicochemical Approaches . . ."
CBBB	Möhwald, <u>Annu. Rev. Phys. Chem.</u> , <u>41</u> , 441-76 (1990) "Phospholipid and Phospholipid-Protein Monolayers At The Air/Water Interface"
CCCC	Murrell et al, "Properties of liquids and solutions", Wiley, p. 276 (1982)
CDDD	Nomura, et al., "US Contrast Enhancement of Hepatic Tumor with Helium Gas Microbubbles: A Preliminary Report," <u>Jpn. J. Med. Ultrasonics</u> , Vol. 18, No. 5, 1991, pp. 444-450
CEEE	O'Hara et al, <u>Journal of Membrane Science</u> , 23 (1985) 1-9, "Preparation of ethylcellulose..."
CFFF	Ohta, et al., <u>Jpn. J. Med. Ultrasonics</u> , Vol. 18, No. 4 (1991), "Effect of the Contrast Agent and the Agitation Met."
CGGG	Ophir, et al., <u>Ultrasound in Med. & Biol.</u> , Vol 15, No. 4, pp. 319-333, 1989, "Contrast Agents in Diagnostic Ultras."
CHHH	Ostro in <u>Spektrum d. Wiss</u> , 94-95, 98 (Marz 1987). "Liposomen . . ."
CIII	Özer et al., <u>Acta Pharm. Tech.</u> <u>34</u> , pp. 129-139 (1988) "Influence of Freezing and Freeze Drying on Stability of Liposome . . ."
CJJJ	Park, et al., <u>Journal of Chemical And Engineering Data</u> , Vol. 27, No. 3 (1982), "Solubility of Gases in Liquids. 14. Bunsen Coefficients for Several Fluorine-Containing Gases (Freons) Dissolved in Water at 298.15K"
CKKK	Peters et al., <u>Am. J. Ophthalmol.</u> <u>100</u> pp. 831-839 (1985) "The non expansive, equilibrated concentration of perfluoropropane in the eye"
LLLL	Puisieux et al., <u>Bull. Soc. Pharm. Bordeaux</u> , <u>123</u> , pp. 111-126 (1984) "Les Liposomes . . ."
CMMM	Rompp Lex. Chemie. 8 Aufl. Stuttgart: Franckh; Bd. Z: Cm-G, (1981): Bd 3; H-L, (1983); Bd 4, M-Pk (1985) "Porositat"
CNNN	Rompps Chemie Lexikon, "Phospholipide"
COOO	Schlieff, <u>Current Opinion in Radiology</u> , 1993, 3:198-207, "Ultrasound Contrast Agents"

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	CPPP	Schneider, et al., Investigative Radiol., <u>26</u> (1), pp. S190-91 (1991) "A New Ultrasound Contrast Agent Based on Biodegradable Polymers Microballoon"
	CQQQ	Schneider, et al., Investigative Radiol., <u>29</u> (2), pp. S149-51 (1991) "The Use of Polymers Microballoons as Ultrasound Contrast Agent . . ."
	CRRR	Swanson, pp. 682-687, "Chapter 22: Enhancement Agents for Ultrasound: Fundamentals," <u>Pharmaceuticals In Medical Imaging</u> , (1990)
	CSSS	Szoka et al, <u>PNAS</u> <u>75</u> , pp. 4194-4198 (Sept. 1978) "Procedure for preparation of Liposomes . . ."
	CTTT	Tomlinson, <u>Int. J. Pharm. Tech. & Prod. Mfr.</u> , <u>4</u> , pp. 49-57 (1983) "Microsphere Delivery Systems . . ."
	CUUU	Ulmius et al, <u>Biochem.</u> , <u>21</u> , p. 1553 (1982) "Molecular organization . . ."
	CVVV	K. Uno, et al., "A new method of preparing monocoed...", <u>J. Microencapsulation</u> , 1984, Vol. 1, No. 1, pp. 3-8
	CWWW	Violante, et al., <u>Investigative Radiology</u> , Vol. 26, Nov. Supp 1991, "Particle-Stabilized Bubbles for Enhanced Organ Ultrasound Imaging"
	CXXX	Voigt et al., "Lzithine" in <u>Lehrb. d. pharm. Tech. i, uberarb. Aufl. - Weinheim; VCH</u> , p. 367 (1979)
	CYYY	Wheatley et al, <u>Biomaterials</u> <u>11</u> , pp. 713-17 (1990) "Contrast agents for diagnostic ultrasound . . ."
	CZZZ	Widder, et al. <u>AJR</u> :147, Aug. 1986, "Microbubbles as Contrast Agent for Neurosonography and Ultrasound . . ."
	CAAAA	Fiedler, <u>Lexikon der Hiffstoffe</u> , 4, Auflage, 1182-85
	CBBBB	Zhang, et al., <u>J. East China Inst. Chem. Tech.</u> , 12(3) 343-345 (1986) "A Study on the Solubilities of F22 and C2F4 in Aqueous Solutions of HCl and NaCl"
	CCCCC	Zeghloul et al, <u>Journal de Chimie Physique</u> , 83; 665-671 (1986) "NMR And Microcalorimetry Study Of The Solubility Of Certain Halons And Their Interaction with Human Serum Albumin"

EXAMINER	DATE CONSIDERED
<p>* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.</p>	